DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality
Information Systems Group
7500 Security Boulevard
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CMS QualityNet (QNet)

Privacy Impact Assessment (PIA)

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QualityNet (QNet) Privacy Impact Assessment (PIA)

System Identification	
Date of this Submission:	November 18, 2003
Title of System:	QualityNet (QNet)
System or Information Collection:	
Unique Project Identifier Number:	
System of Records Number:	
OMB Information Collection Approval Number and Expiration Date:	
Other Identifying Number(s):	

1. Provide an overview of the system or collection and indicate the legislation authorizing this activity.

QualityNet (QNet) is a General Support System (GSS). CMS maintains the QNet network infrastructure, a network environment that uses shared database servers and WAN/LAN resources to monitor and improve utilization and quality of care for Medicare and Medicaid beneficiaries. The program consists of the CMS Data Center Complex 1 located at the CMS central offices in Baltimore, MD; the alternate data center, known as Complex 2, located at the Iowa Foundation for Medical Care (IFMC) in Des Moines, IA; the Internet Complex, also known as Complex 3, located at Buccaneer Computer Systems & Services, Inc. (BCSSI) in Warrenton, VA; a national network of 53 Quality Improvement Organization (QIO) sites responsible for each US state, territory, and the District of Columbia; 2 Clinical Data Abstraction Centers (CDAC); 18 End Stage Renal Disease (ESRD) networks; and the two BCSSI and IFMC Contractor support locations.

Significant Legislation and Regulation of the QualityNet General Support System
This legislation is under the Social Security Act, Title XVIII, Section 1864: "93.777 State Survey and Certification of Health Care Providers and Suppliers"
SEC. 1864. *[42 U.S.C. 1395aa]* (a) The Secretary shall make an agreement with any State which is able and willing to do so under which the services of the State health agency or other appropriate State agency (or the appropriate local agencies) will be utilized by him for the purpose of determining whether an institution therein is a hospital or skilled nursing facility, or whether an agency therein is a home health agency, or whether an agency is a hospice program or whether a facility therein is a rural health clinic as defined in section 1861(aa)(2), a critical access hospital, as defined in section 1861(mm)(1), or a comprehensive outpatient rehabilitation facility as defined in section 1861(cc)(2), or whether a laboratory meets the requirements of paragraphs (16) and (17) of section 1861(s) or whether a clinic, rehabilitation agency or public health agency meets the requirements of subparagraph (A) or (B), as the case may be, of section 1861(p)(4), or whether an ambulatory surgical center meets the standards specified under section 1832(a)(2)(F)(i). To the extent that the Secretary finds it appropriate, an institution or agency which such a State (or local) agency certifies is a hospital, skilled nursing facility, rural health clinic, comprehensive outpatient rehabilitation facility, home

health agency, or hospice program (as those terms are defined in section 1861) may be treated as such by the Secretary. Any State agency which has such an agreement may (subject to approval of the Secretary) furnish to a skilled nursing facility, after proper request by such facility, such specialized consultative services (which such agency is able and willing to furnish in a manner satisfactory to the Secretary) as such facility may need to meet one or more of the conditions specified in section 1819(a). Any such services furnished by a State agency shall be deemed to have been furnished pursuant to such agreement. Within 90 days following the completion of each survey of any health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinic, agency, or organization by the appropriate State or local agency described in the first sentence of this subsection, the Secretary shall make public in readily available form and place, and require (in the case of skilled nursing facilities) the posting in a place readily accessible to patients (and patients' representatives), the pertinent findings of each such survey relating to the compliance of each such health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinic, agency, or organization with (1) the statutory conditions of participation imposed under this title and (2) the major additional conditions which the Secretary finds necessary in the interest of health and safety of individuals who are furnished care or services by any such health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinic, agency, or organization. Any agreement under this subsection shall provide for the appropriate State or local agency to maintain a toll-free hotline (1) to collect, maintain, and continually update information on home health agencies located in the State or locality that are certified to participate in the program established under this title (which information shall include any significant deficiencies found with respect to patient care in the most recent certification survey conducted by a State agency or accreditation survey conducted by a private accreditation agency under section 1865 with respect to the home health agency, when that survey was completed, whether corrective actions have been taken or are planned, and the sanctions, if any, imposed under this title with respect to the agency) and (2) to receive complaints (and answer questions) with respect to home health agencies in the State or locality. Any such agreement shall provide for such State or local agency to maintain a unit for investigating such complaints that possesses enforcement authority and has access to survey and certification reports, information gathered by any private accreditation agency utilized by the Secretary under section 1865, and consumer medical records (but only with the consent of the consumer or his or her legal representative).

(b) The Secretary shall pay any such State, in advance or by way of reimbursement, as may be provided in the agreement with it (and may make adjustments in such payments on account of overpayments or underpayments previously made), for the reasonable cost of performing the functions specified in subsection (a), and for the Federal Hospital Insurance Trust Fund's fair share of the costs attributable to the planning and other efforts directed toward coordination of activities in carrying out its agreement and other activities related to the provision of services similar to those for which payment may be made under part A, or related to the facilities and personnel required for the provision of

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such services, or related to improving the quality of such services. (c) The Secretary is authorized to enter into an agreement with any State under which the appropriate State or local agency which performs the certification function described in subsection (a) will survey, on a selective sample basis (or where the Secretary finds that a survey is appropriate because of substantial allegations of the existence of a significant deficiency or deficiencies which would, if found to be present, adversely affect health and safety of patients), provider entities that, pursuant to subsection (a) or (b)(1) of section 1865, are treated as meeting the conditions or requirements of this title. The Secretary shall pay for such services in the manner prescribed in subsection (b). (d) The Secretary may not enter an agreement under this section with a State with respect to determining whether an institution therein is a skilled nursing facility unless the State meets the requirements specified in section 1819(e) and section 1819(g) and the establishment of remedies under sections 1819(h)(2)(B) and 1819(h)(2)(C) (relating to establishment and application of remedies). (e) Notwithstanding any other provision of law, the Secretary may not impose, or require a State to impose, any fee on any facility or entity subject to a determination under subsection (a), or any renal dialysis facility subject to the requirements of section 1881(b)(1), for any such determination or any survey relating to determining the compliance of such facility or entity with any requirement of this title (other than any fee relating to section 353 of the Public Health Service Act[428]). [427] See Vol. II, P.L. 101-508, §4008(h)(1)(A), with respect to nurse aide training and competency evaluations. [428] See Vol. II, P.L. 78-410, §353.
This legislation is under Title XI of the Social Security Act, Part B, as amended by the Peer Review Improvement Act of 1982.
Section 1902 (a)(30)(A) of the Social Security Act (the Act) requires that State Medicaid Agencies provide methods and procedures to safeguard against unnecessary utilization of care and services and to assure "efficiency, economy and quality of care." Under section 1902 (d), a State can contract with a PRO or PRO-like entity to perform medical and utilization review functions required by law. The contracts must be consistent with the PRO legislation. Section 1903 (a)(3)(C) of the Act specifies that 75% Federal Financial Participation is available for State expenditures for the performance of medical and utilization reviews or external quality reviews by a PRO, or by entity, which meets the requirements of section 1152 of the Act (i.e., "PRO-like entity").
Section 1902 (a)(30)(C) of the Act requires the performance of an annual, independent, external review of the quality of services furnished under each State contract with a Managed Care Organization (MCO) that is governed by section 1903 (m) of the Act. Section 1902 (a)(30)(C) further specifies that only three types of organizations are permitted to perform this review: 1) a PRO that has a contract with the Secretary to

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perform Medicare reviews; 2) an organization which is determined by the Secretary to meet the requirements for qualifying as a PRO contained in section 1152 of the Act (i.e.; a PRO-like entity); and 3) a private accreditation body. This legislation is under Title XI--General Provisions, Peer Review, and Administrative Simplification[1]
SEC. 1154. *[42 U.S.C. 1320c-3]* (a)(7)(c) Any utilization and quality control peer review organization entering into a contract with the Secretary under this part must perform the following functions: (7) The organization, to the extent necessary and appropriate to the performance of the contract, shall-- (C) examine the pertinent records of any practitioner or provider of health care services providing services with respect to which such organization has a responsibility for review under paragraph (1);
SEC. 1154. *[42 U.S.C. 1320c-3]* (a)(9) Any utilization and quality control peer review organization entering into a contract with the Secretary under this part must perform the following functions: (9)(A) The organization shall collect such information relevant to its functions, and keep and maintain such records, in such form as the Secretary may require to carry out the purposes of this part, and shall permit access to and use of any such information and records as the Secretary may require for such purposes, subject to the provisions of section 1160. (B) If the organization finds, after reasonable notice to and opportunity for discussion with the physician or practitioner concerned, that the physician or practitioner has furnished services in violation of section 1156(a) and the organization determines that the physician or practitioner should enter into a corrective action plan under section 1156(b)(1), the organization shall notify the State board or boards responsible for the licensing or disciplining of the physician or practitioner of its finding and of any action taken as a result of the finding.
The Balanced Budget Act of 1997 created section 1932 (c)(2) of the Act, which would replace section 1902 (a)(30)(C) with a new requirement for annual, external quality review (EQR) of Medicaid MCOs. In this new requirement, States are no longer restricted to using PRO, PRO-like and accrediting organizations to perform EQR; States may contract with "qualified, independent" entities. CMS has specified requirements for qualifications and independence in a Notice of Proposed Rulemaking, published on December 1, 1999. When this rule becomes final, the PRO-like designation will no longer have any applicability to statutory requirements for this annual, independent, external review of Medicaid MCO quality.

2. Describe the information the agency will collect and how the agency will use the collected

information. Explain how the data collected are the minimum necessary to accomplish the purpose for this effort.

The QNet WAN/LAN network configuration provides the WAN/LAN connectivity and support for the Health Care Quality Improvement System that comprises of three Major Applications that collect information and operate within QNet network infrastructure:

- Standard Data Processing System (SDPS)
- Consolidated Renal Operations in a Web-Enabled Environment (CROWN)
- Quality Improvement Evaluation System (QIES)

Refer to Health Care Quality Improvement Systems Privacy Impact Assessment (PIA).

The Standard Data Processing System (SDPS) consists of many data and reporting requirements and was designed and developed in immediate response to the ongoing ADP requirements of the various Quality Improvement Organizations (QIOs) and other affiliated partners, such as the Clinical Data Abstraction Centers (CDACs) to fulfill their contractual requirements with CMS. This system, which became operational in May 1997, interfaces with CMS Central Office, 53 QIOs and CDACs. Through the SDPS, the QIOs have a data base of current Part A claims data, ad-hoc capability to access Part B data, access to national data sets, software tools for data analysis, report generation tools, and project information.

The Consolidated Renal Operations in a Web-enabled Network (CROWN) will facilitate the collection and maintenance of information about the Medicare End Stage Renal Disease (ESRD) program.

CROWN is being developed to modernize the collection and retrieval of ESRD data in a secure, Web-enabled environment. The new capabilities will allow dialysis facilities to enter information electronically and transmit it to the appropriate ESRD Network, and CMS also will be able to send feedback to the Networks and the facilities through the new environment. CROWN consists of the following major modules:

- The Vital Information System to Improve Outcomes in Nephrology (VISION), which will support electronic data entry and encrypted transmission of ESRD patient and facility data from dialysis facilities directly to their Networks via a secure, Web-enabled environment called "QNet Exchange";
- The ESRD Standard Information Management System (SIMS), supports the business processes of the ESRD Network Organizations and provides communication and data exchange links among the Networks, the facilities, and CMS, via the QNet Exchange; and
- The Renal Management Information System (REMIS), to replace CMS's existing Renal Beneficiary and Utilization System (REBUS), which determines the Medicare coverage periods for ESRD patients and serves as the primary mechanism to store and access ESRD patient and facility information in the ESRD Program Management and Medical Information System Database.

Quality Improvement and Evaluation System (QIES) initiative establishes CMS's goals for the standardization of the Minimum Data Set/Outcome and Assessment Information Set (MDS/OASIS) systems. QIES will provide states with the ability to collect assessment data from providers and transmit that data to a central repository for analysis and support of prospective payment systems. CMS intends that the MDS/OASIS data management system will support a suite of applications/tools designed to provide states and CMS with the ability to use performance information to enhance on-site inspection activities, monitor quality in an ongoing manner, and facilitate providers' efforts related to continuous quality improvement.

3. Explain why the information is being collected.

The Quality Improvement System for Managed Care (QISMC) standards and guidelines are key tools for use by CMS and States in implementing the quality assurance provisions of the Balanced Budget Act of 1997 (BBA), as amended by the Balanced Budget Refinement Act of 1999. The QISMC standards and guidelines are intended to achieve four major goals:

- To clarify the responsibilities of CMS and the States in promoting quality as value-based purchasers of services for vulnerable populations.
- To promote opportunities for partnership among CMS and the States and other public and private entities involved in quality improvement efforts.
- To develop a coordinated Medicare and Medicaid quality oversight system that would reduce duplicate or conflicting efforts, and send a uniform message on quality to organizations and consumers.
- To make the most effective use of available quality measurement and improvement tools, while allowing sufficient flexibility to incorporate new developments in the rapidly advancing state of the art.

http://www.cms.hhs.gov/cop/2d1.asp

The QNet WAN/LAN infrastructure supports the following CMS organizational business processes and data collection requirements:

- The capability for collection and management of clinical, survey, and project data from Medicare and Medicaid providers.
- The management and analysis of that clinical, survey, and project data with various SDPS programs by the Quality Improvement Organization (QIO).
- The collection of data by ESRD Network Organizations to administer the national Medicare ESRD program.
- The collection of provider and beneficiary-specific outcomes of care and performance data using QIES across a multitude of delivery sites (such as nursing homes and Rehabilitation and Long Term Care Hospitals, etc.) for use to improve the quality and cost effectiveness of services provided by the Medicare and Medicaid programs.

- The management and provision of Medicare and Medicaid information to providers that include but are not limited to Hospitals, physician or family practice clinics, dialysis clinics, Skilled Nursing Facilities, Home Health Agencies, and various specialized clinics.

4. Identify with whom the agency will share the collected information.

Refer to Health Care Quality Improvement Systems Privacy Impact Assessment (PIA).

5. Describe how the information will be obtained, from whom it will be collected, what the suppliers of information and the subjects will be told about the information collection, and how this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). Describe any opportunities for consent provided to individuals regarding what information is collected and how the information will be shared.

Refer to Health Care Quality Improvement Systems Privacy Impact Assessment (PIA).

6. State whether information will be collected from children under age 13 on the Internet and, if so, how parental or guardian approval will be obtained. (Reference: Children's Online Privacy Protection Act of 1998)

Refer to Health Care Quality Improvement Systems Privacy Impact Assessment (PIA).

7. Describe how the information will be secured.

The CMS QNet network infrastructure security policy is guided by Internet Communications Security and Appropriate Use Policy and Guidelines for HCFA Privacy Act-protected and other Sensitive HCFA Information, November 24, 1998.

http://www.cms.hhs.gov/it/security/docs/internet_policy.pdf

8. Describe plans for retention and destruction of data collected.

CMS Information Systems Security Policy, Standards and Guidelines Handbook, Version 1, February 19, 2002 is the policy document for the CMS AIS Security Program. It serves as the primary source of Information Technology (IT) systems security information for all CMS IT users. The policies, standards and guidelines described therein apply to all users of CMS hardware, software, information, and data. The CMS AIS Security Program ensures the existence of adequate safeguards to protect personal, proprietary, and other sensitive data in automated systems and ensures the physical protection of all CMS General Support Systems (GSSs) and Major Applications (MAs) that maintain and process sensitive data.

http://www.cms.hhs.gov/it/security/docs/handbook.pdf

9. Identify whether a system of records is being created under section 552a of Title 5, United States Code (the Privacy Act), or identify the existing Privacy Act system of records notice

under which the records will be maintained.

CMS has the authority to collect and use personally identifiable information that is relevant and necessary to accomplish the purpose of the agency (defined as the Department of Health and Human Services) under the provisions of the Privacy Act of 1974 (5 U.S.C. 552a). The Privacy Act requires that the agency maintain all records in system of records and inform the public of the establishment or revision of a system of record through publication in the Federal Register.

QualityNet General Support System (GSS) Network Infrastructure
No Systems of Records exists.

The QNet Infrastructure was designed with the following goals taken into consideration:

- Reliability: To provide a dependable infrastructure for user services and network applications.
- Scalability: To support future deployment of planned network applications.
- Robustness: To provide a redundant network to access to mission critical applications.

QNet has been in production for several years and consists of a unified frame relay network for connecting eighty-plus (80+) sites. The current design of the QNet Infrastructure is a hybrid model with a multi-tiered topology. Facilities are being leased from multiple service providers such as AT&T (CMS MDCN), WorldCom (MCI/vBNS+), and Global Crossing (Internet Service Provider). The AT&T IP network forms the Center for Medicare and Medicaid Services' (CMS) Medicare Data Communication Network (MDCN) and provides Wide-Area-Network (WAN) links to 50+ site locations nationwide. The MCI/vBNS+ network provides the WAN links between Complex 1 in Baltimore, MD; Complex 2 in West Des Moines, IA; and Complex 3 in Warrenton, VA. Global Crossing is the QNet Internet Service Provider (ISP).

Endorse	**Endorse**	**Approve**
_/s/_____	____/s/_____	____/s/_____
J. Ned Buford CMS Privacy Officer	Timothy P. Love Chief Information Officer	Thomas A. Scully CMS Administrator
Date_11/21/2003_____	Date _11/21/2003_____	Date _11/21/2003__